American Dietetic Association

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Research and Professional Briefs

Efficacy of a Meal-Replacement Program for Promoting Blood Lipid Changes and Weight and Body Fat Loss in US Army Soldiers

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ABSTRACT

Excess weight is associated with negative health outcomes. Meal replacements are effective in promoting favorable body composition changes in civilian populations; however, their efficacy with military service members who have unique lifestyles is unknown. The objective of this randomized controlled trial was to determine the efficacy of the Army's education-based weight-management program, "Weigh to Stay," with and without meal replacements for improving blood lipids, and to promote weight and body fat loss in overweight US Army soldiers. Soldiers (n=113; 76 males/37 females) attending Weigh to Stay at Fort Bragg, NC, in 2006/2007 were randomized to Weigh to Stay only or a commercially available meal-replacement program (two meal replacements per day) in conjunction with Weigh to Stay, and followed until Army body fat standards were met or for 6 months if standards were not met. Study completers (n=46) in both treatment groups lost weight (Weigh to Stay: −2.7±4.3 kg; meal replacers: −3.8±3.5 kg) and fat mass (Weigh to Stay, −2.7±3.2 kg; meal replacers: −2.9±2.5 kg), and improved high-density lipoprotein cholesterol concentrations (Weigh to Stay: 13±9 mg/dL [0.34±0.23 mmol/L]; meal replacers: 8±7 mg/dL [0.21±0.18 mmol/L]; $P<0.05$); however, no between-group differences were observed. Attrition was lower ($P=0.009$) and success in meeting body fat standards tended to be higher ($P=0.06$) for the meal replacers vs Weigh to Stay participants. Intent-to-treat analysis demonstrated that meal replacers lost more weight (1.2±0.5 kg), percent body fat (1.0%±0.4%), and fat mass (0.8±0.4 kg) compared to Weigh to Stay volunteers ($P<0.05$). Our findings suggest that meal replacement use can be recommended as a potential adjunct strategy to Weigh to Stay.

J Am Diet Assoc. 2010;110:268-273.

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Manuscript accepted: June 30, 2009.

Published by Elsevier Inc. on behalf of the American Dietetic Association.

0002-8223/10/11002-0010$0.00/0

doi: 10.1016/j.jada.2009.10.039

Approximately 65% of Americans are overweight or obese (1). US military service members are not immune to this epidemic. From 1995 to 2005, the prevalence of overweight among Department of Defense military personnel increased from 51% to 61% with 12% identifying as obese (body mass index [calculated as kg/m^2] ≥30) (2). As such, the prevalence of overweight and obesity in US military personnel remains a primary concern of the Department of Defense. Obesity not only increases chronic disease (2) and injury (3-5) risk, but also burdens the military health care system (6) and can impact military operational readiness.

The Army mandates that soldiers meet age and sex-specific weight-for-height and percent body fat standards as defined in the Army Weight Control Program regulations (7). If a soldier exceeds their body fat standard after failing to meet weight-for-height standards, he or she is administratively enrolled in the Army Weight Control Program until compliant (7). Self-report data and unannounced anthropometric assessments indicate that 11% to 28% of soldiers are noncompliant with Army body-composition standards (8-10), although only 4% of Army personnel actually report being enrolled in the Army Weight Control Program (2). Overweight soldiers have strong incentive to show satisfactory progress (ie, defined as 3- to 8-lb monthly weight loss) and meet body composition standards, because those enrolled and unsuccessful in the Army Weight Control Program can be denied opportunities for career advancement, military schooling, and pay raises, and ultimately can be discharged from military service.

The "Weigh to Stay" program is a mandated education-based lifestyle-modification program designed to help soldiers on the Army Weight Control Program meet body-composition standards. The efficacy of the Weigh to Stay program in helping overweight soldiers meet Army body-composition standards is unknown, and despite access to

Report Documentation Page

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
JUN 2009		**00-00-2009 to 00-00-2009**

4. TITLE AND SUBTITLE	5a. CONTRACT NUMBER
Efficacy of a Meal-Replacement Program for Promoting Blood Lipid Changes and Weight and Body Fat Loss in US Army Soldiers	5b. GRANT NUMBER
	5c. PROGRAM ELEMENT NUMBER
6. AUTHOR(S)	5d. PROJECT NUMBER
	5e. TASK NUMBER
	5f. WORK UNIT NUMBER
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) **US Army Research Institute of Environmental Medicine,Kansas Street, Building 42,Natick,MA,01760**	8. PERFORMING ORGANIZATION REPORT NUMBER
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)	10. SPONSOR/MONITOR'S ACRONYM(S)
	11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION/AVAILABILITY STATEMENT
Approved for public release; distribution unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
see report

15. SUBJECT TERMS

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			
unclassified	**unclassified**	**unclassified**	**Same as Report (SAR)**	**6**	

this program, overweight soldiers report experimenting with various weight-loss strategies, including liquid meal replacements (11). The efficacy of meal-replacement programs as a successful adjunct intervention for weight control has been demonstrated in civilian populations (12-18). The calorie-controlled portion sizes and convenience of meal replacements (19) may fit nicely into the unique on-the-go lifestyle of many military service members, often characterized by rigid, nontraditional work schedules and multiday field training exercises. Therefore, the Weigh to Stay program may be more effective in promoting sustained weight loss when combined with a meal replacement program.

The Institute of Medicine recommends that the military services evaluate new and existing weight-management programs (20); however, efficacy of the Weigh to Stay program is unknown. Therefore, the purpose of this study was to determine the efficacy of both Weigh to Stay and Weigh to Stay combined with meal replacements for weight and body fat loss among soldiers exceeding body fat standards. It was hypothesized that Weigh to Stay plus meal replacements would be more effective than Weigh to Stay alone in helping soldiers meet weight loss requirements and achieve body fat standards.

METHODS

Subjects

Volunteers were recruited at the first of three required Weigh to Stay sessions at Womack Army Medical Center, Fort Bragg, NC, and provided written consent to participate after an explanation of study procedures and risks. Volunteers who were ≥2% above their age- and sex-specific percent body fat standard as measured by circumference-based Army prediction equations (7) and were free of medical conditions affecting metabolism, appetite, or capacity for physical activity were eligible to participate. Soldiers who had attended the Weigh to Stay program within the past year, were pregnant or ≤180 days postpartum, were likely to leave military service within 1 year, or were deploying within 6 months were excluded. The study protocol was approved by the Human Use Review Committee, US Army Research Institute of Environmental Medicine, Natick, MA; the Institutional Review Board, Womack Army Medical Center, Fort Bragg, NC; and the Clinical Investigation Regulatory Office, Fort Sam Houston, TX. The investigators adhered to the policies for protection of human subjects as prescribed in Army Regulations 70-25 and 40-38, and US Army Medical Research and Materiel Command Regulation 70-25. The research was conducted in adherence with the provisions of 32 Code of Federal Regulations Part 219.

Experimental Design

Using commercially available software (Microsoft Excel version 11, 2003, Redmond, WA), volunteers were randomized to receive either the Weigh to Stay program alone or a commercially available meal-replacement program in addition to Weigh to Stay. Because the purpose of this study was to help volunteers meet Army body fat standards, the intervention continued until the volunteer either complied with the standard or failed to make satisfactory progress (ie, <1.5-kg weight loss after 6 months). Outcome measures included weight, body composition, fasting blood lipid concentrations, and average daily energy intake and expenditure. Volunteer compliance and satisfaction with each intervention was assessed by survey at study completion. Compliance was self-reported; assessed by the question, "How often did you follow your personalized [Weigh to Stay or meal replacement] weight loss plan as you were instructed?" Response options were: "<1 days/week," "1-2 days/week," "3-5 days/week," or "6-7 days/week." Satisfaction was defined as an affirmative response to the question, "Do you think the [Weigh to Stay or meal replacement] program is an effective way to lose weight?"

Dietary Interventions

Weigh to Stay. The Weigh to Stay program was comprised of three educational sessions typically completed within a 2-week period: a nutrition education class taught by a registered dietitian (RD), an exercise education class taught by a physical therapist, and a private counseling session with an RD. The 1- to 2-hour classes covered general health behavior topics related to nutrition and exercise, while the private session provided 30 to 60 minutes of individualized nutrition counseling, including meal plan development, and food record review. Participants were also provided with a brochure containing basic nutrition education for weight management. Volunteers were not given additional individualized education unless they scheduled an appointment with a hospital RD.

Weigh to Stay Plus Meal Replacements. In addition to completing the Weigh to Stay program outlined here, the meal-replacement group received an individualized meal-replacement program (Slim-Fast Plan, Unilever, Englewood Cliffs, NJ) and were provided with all meal-replacement products and snack bars (Slim-Fast Optima, Unilever). This group will be referred to as "meal replacers" throughout the article. Meal replacers were provided with calorie-controlled meal plans based on initial body weight and adjusted periodically based on weight-loss rate (Table 1) in addition to education regarding low-fat food preparation techniques, healthful recipes, and suggestions for grocery shopping and dining out.

Outcome Measures

All outcome measures were assessed at baseline and at time points during the intervention indicated here. Height was measured at baseline only to the nearest 0.1 cm using a stadiometer (Seca 214, Seca Ltd, Vogel & Halke, Hamburg, Germany) and weight was measured monthly to the nearest 0.1 kg using a calibrated scale (Seca 770, Seca Ltd) with volunteers in shorts and t-shirt. All measurements of height and weight were recorded as the average of two measurements. Body composition was assessed by dual-energy x-ray absorptiometry (Hologic model QDR 4500W densitometer, Hologic Inc, Bedford, MA) bimonthly. Body fat percentage was calculated monthly from circumference-based prediction equation by trained personnel following procedures in the Army Weight Control Program regulation (7). Male circumference sites were the neck and abdomen II. Female circumference

Table 1. Daily individualized dietary plan for soldiers in the US Army Weight Control Program who received meal replacements as an adjunct to the standard program treatment

Current weight (lb)	Prescribed energy intake (kcal/d)	Dietary plan
Up to 140	1,300	1 meal replacement 1 meal replacement+conventional food (~200 kcal) 1 sensible meal[a] (~500 kcal) 3 fruits or vegetables
141-170	1,500	1 meal replacement 1 meal replacement+conventional food (~200 kcal) 1 sensible meal[a] (~500 kcal) 4 fruits or vegetables 1 snack[b] (~120 kcal)
171-200	1,700	1 meal replacement 1 meal replacement+conventional food (~200 kcal) 1 sensible meal[a] (~500 kcal) 4 fruits or vegetables 3 snacks[b] (~120 kcal each)
>200	1,900	1 meal replacement 1 meal replacement+conventional food (~200 kcal) 1 sensible meal[a] (500 kcal) 5 fruits or vegetables 4 snacks[b] (~120 kcal each)

[a]Selected from conventional foods (lean protein, whole-grain carbohydrates, vegetables, and fruits).
[b]Selected from either conventional foods or snack bars (Slim-Fast Optima, Unilever, Englewood Cliffs, NJ).

sites were the neck, abdomen I, and hip. Success in meeting body fat standards was determined according to the Army Weight Control Program regulation: maximum allowable percent body fat for males 18-20, 21-27, 28-39, and older than 40 years old is 20%, 22%, 24%, and 26%, respectively; maximum allowable percent body fat for females 18-20, 21-27, 28-39, and older than 40 years is 30%, 32%, 34%, and 36%, respectively.

Fasted blood samples were obtained following a 12-hour fast at baseline and every 3 months thereafter, and analyzed for total cholesterol, triacylglycerols, and high-density lipoprotein-cholesterol. Low-density lipoprotein-cholesterol was calculated using the Friedewald equation (21). The Womack Army Medical Center laboratory participates in the College of American Pathologists Survey for quality assurance and complies with standards established by the Joint Commission.

Energy intake and energy expenditure were determined from self-reported 3-day food and activity records at baseline and following the intervention. RDs provided standardized food record instructions using food models and portion-size aids. Food records were reviewed for completeness in one-on-one interviews between the volunteer and an RD trained in food record analysis. Any deficiencies in recording, including incomplete item descriptions and preparation methods, vague food/beverage descriptions, and missing quantities were resolved. Trained RDs analyzed food records for dietary energy and macronutrient content using Food Processor (Food Processor SQL version 10.0, 2006, ESHA Research, Salem, OR). To maintain quality control, 25% of completed food records were selected and reviewed for accuracy by a second RD. Electronically recorded activity records gathered using personal digital assistance-based software (BalanceLog, version 2.0, 2002, Microlife USA, Inc, Dunedin, FL) were analyzed for total daily energy expenditure. Volunteers record activity by selecting from >300 activities in the Balance Log database and specifying activity duration. The software derives an estimate of daily energy expenditure using volunteer-logged physical activities and estimated resting energy expenditure (REE) multiplied by a factor accounting for activities of daily living. All volunteer entries in BalanceLog were reviewed for accuracy and completeness by an RD at the time of record review.

Statistical Analysis: Study Completers and Intent-to-Treat

In this investigation, study completers were defined as volunteers who either succeeded in meeting their age- and sex-specific body fat standards at any time during the intervention or volunteers who did not meet their body fat standards but remained in the study for at least 6 months. Intent-to-treat analysis was used in order to minimize bias due to high attrition rate and differences in attrition rate between groups (22), and included all volunteers with baseline value carried forward. Statistical analysis was completed using the SPSS Inc Statistical Package (version 15.0, 2006, SPSS Inc, Chicago, IL). All data were examined visually and using statistical software for errors including incomplete data, typographical mistakes, and duplicate entry prior to analysis. Normality was determined using the Shapiro-Wilk test in conjunction with histogram analysis. Differences in dependent variables (eg, weight, body composition, and blood lipids) were assessed using Student's independent and paired samples t test for differences between and within groups, respectively. For categorical data (eg, success or failure in meeting percent body fat standards), χ^2 tests were used. All results are presented as mean±standard deviation; significance was established a priori at $P<0.05$.

RESULTS AND DISCUSSION

Of the 126 potential volunteers screened, 113 (76 males and 37 females) met all eligibility requirements and were enrolled. Racial distribution was similar between groups (Weigh to Stay, n=35 white, 19 black, 2 other; meal replacers, n=35 white, 16 black, 4 other). Forty-six volunteers (Weigh to Stay, n=12 males, 5 females; meal replacers, n=21 males, 8 females) completed the study; age (27.5±7.3 and 28.9±7.5 years) and duration of study participation was similar between groups (5.7±2.1 and 5.0±2.5 months).

Overall attrition was 59% (n=67 of 113) with attrition for Weigh to Stay significantly higher than meal replacers (70% and 48%; $P<0.05$). Sixty-six percent withdrew in the first 2 months of the study (Weigh to Stay, n=29;

Table 2. Changes in weight, body composition, and blood lipids among US Army soldiers participating in the US Army Weight Control Program (AWCP) or a modified AWCP which included meal replacements[a]

	Weigh to Stay Only				Meal Replacers			
	n	Pre	Post	Change	n	Pre	Post	Change
		← mean±standard deviation →				← mean±standard deviation →		
Study completers								
Weight (kg)	17	94.9±13.3	92.2±12.9	−2.7±4.4[b*]	29	98.6±16.1	94.8±15.5	−3.8±3.5[b***]
Weight change (%)	17	—	—	−2.8±4.1	29	—	—	−3.9±3.0
BMI[c]	17	32.0±3.1	31.9±3.0	−0.1±3.6	29	33.2±3	32.1±3	−1.1±4.8
Body fat (%), CIRC[d]	17	31.4±6.6	28.5±6.7	−2.9±2.4[b***]	29	31.4±5.9	27.8±5.6	−3.6±2.2[b***]
Body fat (%), DEXA[e]	10	32.0±4.2	30.2±4.9	−1.8±2.1[b*]	24	31.5±5.9	29.7±6.0	−1.8±1.9[b***]
Fat mass (kg)	10	29.4±3.9	26.7±4.3	−2.7±3.2[b*]	24	30.3±5.9	27.4±5.7	−2.9±2.5[b***]
Lean mass (kg)	10	60.7±12.0	59.6±11.1	−1.1±1.9	24	64.3±13.8	63.3±13.2	−1.0±2.2[b*]
LDL[f] (mg/dL)[g]	5	118.0±25.7	117.6±21.7	0.4±28.7	14	122.9±37.6	103.9±30.7	−19.0±25.1[b**]
HDL[h] (mg/dL)[g]	5	40.2±8.3	52.8±11.7	12.6±9.0[b*]	14	42.9±12.0	51.3±14.5	8.4±6.9[b***]
Energy intake (kcal/d)	17	1,873±759	1,677±662	−196±823	29	1,945±627	1,592±434	−353±504[b*]
Energy expenditure (kcal/d)	17	2,663±531	2,397±381	−265±370	29	2,912±604	2,948±676	+36±457
All volunteers[a]								
Weight (kg)	56	99.1±14.1	98.3±14.3	−0.81±2.6[b*]	57	98.0±16.4	96.1±16.1	−2.0±3.2[b***i*]
BMI	56	33.1±2.9	32.0±3.0	−1.1±1.1	57	33.1±3	31.9±3	−1.2±1
Body fat (%), CIRC	56	31.6±6.2	30.7±6.4	−0.86±1.9[b***]	57	32.9±5.9	31.0±6.5	−1.9±2.4[b***i**]
Body fat (%), DEXA	56	31.1±4.5	30.7±4.7	0.42±1.1[b**]	57	32.5±5.7	31.6±6.0	−0.87±1.6[b***]
Fat mass (kg)	56	29.9±5.4	29.5±5.8	−0.4±1.7[b**]	57	30.7±5.0	29.4±5.3	−1.3±2.2[b***i*]
Lean mass (kg)	56	64.2±10.7	64.0±10.6	−0.2±0.1[b*]	57	62.6±13.9	62.1±13.8	−0.5±1.5[b*]

[a]Includes all volunteers randomized to a treatment group (ie, data analyzed via intent-to-treat, first observation carried forward).
[b]Indicates significant within-group difference.
[c]BMI=body mass index (calculated as kg/m^2).
[d]DEXA=dual x-ray absorptiometry.
[e]CIRC=Department of Defense circumference-based body fat prediction equations.
[f]LDL=low-density lipoprotein cholesterol.
[g]To convert mg/dL cholesterol to mmol/L, multiply mg/dL by 0.026. To convert mmol/L cholesterol to mg/dL, multiply mmol/L by 38.7. Cholesterol of 193 mg/dL=5.00 mmol/L.
[h]HDL=high-density lipoprotein cholesterol.
[i]Indicates significant difference between Weigh to Stay and meal replacers ($P<0.05$).
*$P<0.05$.
**$P<0.01$.
***$P<0.001$.

meal replacers, n=15). Thirty-nine volunteers were withdrawn from the study for failure to attend data-collection appointments, while others left for medical reasons unrelated to the intervention (n=10), military discharge (n=2), lack of time because of unit training (n=5), or dissatisfaction with weight loss (n=3). Ten volunteers did not provide a reason for withdrawal. There were no differences in sex, age, race, weight, height, percent body fat, fat mass, and fat-free mass between study completers and dropouts.

The attrition rate in this study was similar for meal replacers, but higher in Weigh to Stay participants, compared to attrition rates in weight-loss intervention studies (up to 46%) conducted in civilian populations 3 to 12 months in duration (12,14,16-18,23). Overall attrition may have been higher in this study compared to previous studies because of routine geographical relocations and deployments of military personnel. The difference in attrition rates between the meal replacers and Weigh to Stay participants suggests the novelty and efficacy of meal replacements were potential motivators to study adherence.

Dietary Intervention Compliance and Satisfaction in Study Completers

Completion rate of all three sessions included in the Weigh to Stay program (Weigh to Stay: n=14 [82%] vs meal replacers: n=20 [69%]) and the number of volunteers who visited a hospital RD at least one time during the study (Weigh to Stay: n=7 [41%] vs meal replacers: n=8 [28%]) did not differ between groups. Self-reported compliance and satisfaction with the study intervention was assessed in only 70% of study completers (Weigh to Stay, n=9; meal replacers, n=23) because of time constraints of some of the volunteers. One volunteer in Weigh to Stay and three meal replacers reported complying with their personalized weight loss plan 6 to 7 days/week, while 35% (n=8) and 61% (n=14) complied 3 to 5 days/week, respectively. The remaining volunteers followed their plan <3 days/week or did not specify whether they followed their plan. In meal replacers, 61% (n=14) consumed meal replacements as recommended (2 meals/day), while 39% (n=9) consumed meal replacements less frequently. Satisfaction with both programs was high, as 78% of Weigh to Stay volunteers (n=7) and 91% of meal replacers (n=21) reported that the Weigh to Stay or meal-replacement program, respectively, was an effective weight-loss program.

Body Composition and Blood Lipid Changes

Baseline and postintervention outcome measures for study completers and all volunteers (ie, intent-to-treat analysis) are presented in Table 2. For study completers, volunteers in both groups lost weight and body fat, gained

lean mass, and demonstrated favorable blood lipid profile changes. Meal replacers substantially reduced energy intake while Weigh to Stay volunteers had overall lower mean energy intake, although the decline in the Weigh to Stay group was not statistically significant. There were no between-group differences amid treatment groups at either baseline or postintervention for any variable.

In order to minimize withdrawal bias because of high attrition and differences in attrition between groups, an intent-to-treat analysis including all volunteers was completed (n=113; Weigh to Stay, n=57; meal replacers, n=56). Within-group changes in weight, body fat, and lean mass were attenuated but remained significant (Table 2). Meal replacers lost more weight (P=0.04) and body fat (P=0.01) than Weigh to Stay participants.

The observation in study completers that adherence to a hypocaloric diet employing meal replacements was equally effective in promoting weight loss in overweight volunteers compared to a hypocaloric diet alone is in agreement with some (14-18) but not all (12,13,15) previous reports. Between-group differences observed in this study are less robust compared to previous studies that observed a 4- to 6-kg greater weight loss when volunteers incorporated meal replacements into a hypocaloric diet program (12,13,15). Inconsistencies may be attributed to differences in volunteer populations and study designs. This study was particularly unique in that the population was comprised mainly of young males, reflecting US Army demographics; whereas previous studies demonstrating higher weight-loss efficacy with meal replacements involved primarily overweight and obese middle-aged females (12,13,15). Some studies suggest that males lose more weight compared to females in response to negative energy balance induced by exercise (24,25); the impact of sex has not been reported in studies investigating the efficacy of meal replacements for weight loss (12-18). Previous studies may not have included males because it may be more socially acceptable for females to use meal-replacement products. The 21 male study completers in the meal replacers group, however, suggest that male soldiers may be willing to adopt a meal-replacement program. Unfortunately, the sample size in this study does not permit analysis of between-sex differences. Difference in lifestyle between soldiers and civilians may also explain the discrepant findings; soldiers tend to have rigid, nontraditional work schedules and participate in multiday field training exercises. Furthermore, in contrast to previous studies in which dependent variables (ie, weight loss, blood lipid change) are typically measured during a predetermined time period, this study was designed to provide a dichotomous outcome (success vs failure). Volunteers in this trial were removed from the intervention once they met their body fat standard, making comparisons to previous studies difficult.

By establishing a definition of success, this study was able to investigate the efficacy of Weigh to Stay, and compare the efficacy of both programs for helping soldiers meet Army body fat standards. The average time it took to meet body fat standards was 3±2 months and was similar between the Weigh to Stay and meal replacers (P=0.45). Weigh to Stay alone was successful in promoting weight and body fat loss; however, only 24% (n=4) of volunteers were successful in meeting body fat standards. In contrast, the addition of meal replacements trended toward a higher success rate (n=15 [52%]; P=0.06). The intent-to-treat analysis revealed that meal replacers (n=15 [27%]) were more successful in meeting body fat standards compared to Weigh to Stay (n=4 [7%]; P=0.006), suggesting adding meal replacements to the Weigh to Stay program is more effective in a military population.

Limited sample size and suboptimal compliance may have masked any significant differences between groups for study completers. The final sample size was adequate based on a priori estimations, indicating that 17 volunteers in each group would be required to have an 84% chance of detecting a 3-kg difference in body weight loss between groups (α=.05). However, this estimation was based on body weight changes, not success in meeting body fat standards. Further, although more than half of the study completers in the meal-replacement group consumed meal replacements as recommended (ie, two meals per day), and reportedly complied with their individualized meal plan 3 to 5 days per week, compliance 6 to 7 days per week was low. It is possible that volunteers in the meal-replacement group overate on the days where they were noncompliant, thereby attenuating the total energy deficit created on the meal-replacement program. Missing data, particularly for blood lipid and dual-energy x-ray absorptiometry measurements, was another limitation of this study. Logistical conflicts with military-specific duties and inconsistent support of commanding officers may have contributed to poor attendance at study appointments. Because meal replacers had the added motivation of receiving their meal-replacement products at biweekly appointments, these volunteers were more likely to accommodate the time requirements for biochemical and dual-energy x-ray absorptiometry measurements.

Finally, the findings of this trial are limited by the lack of a control group for comparison to the Weigh to Stay participants. However, because Army regulations mandate that soldiers who exceed their body fat standard enroll in the Weigh to Stay program, and soldiers noncompliant with Army standards and regulations are subject to punitive actions, including discharge from service, inclusion of a control group would be unethical.

CONCLUSIONS

Based on the overall findings, meal-replacement use can be recommended as a potential adjunct strategy to Weigh to Stay for some soldiers. Future studies should focus on investigating the efficacy of more intensive interventions (eg, more frequent weigh-ins and body fat measurements and additional follow-up appointments with an RD), as well as the barriers and motivators to weight and body fat loss in a military population.

STATEMENT OF POTENTIAL CONFLICT OF INTEREST: No potential conflict of interest was reported by the authors.

FUNDING/SUPPORT: Meal-replacement products used in this study were provided by Unilever.

ACKNOWLEDGEMENTS: The authors would like to thank Crystal Ross for her hard work as the study coordinator; CPT Trisha Stavinoha for her expertise as a

research dietitian; MAJ Lolitta Burrell, LTC Joanna Reagan, and LTC LesLee Sanders for their supervisory support; and most importantly, our volunteers. Authors would also like to acknowledge the contribution of Unilever for providing the meal replacement products used in this study.

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